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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/563,277 | 07/13/2006 | Catherine Primard-Brisset | REGIM 3.3-071 | 4304 |
| 530 | 7590 | 04/27/2009 | EXAMINER | |
| LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | FOX, DAVID T | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|------------------------|------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/563,277 | PRIMARD-BRISSET ET AL. | |
| | Examiner | Art Unit | |
| | David T. Fox | 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 January 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 37-47 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 37-47 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 04 January 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/165/08)
 Paper No(s)/Mail Date 19 December 2006

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____

Restriction/Election

Applicant's election of Group I with traverse in the response filed 02 January 2009 is noted. Applicant asserts that claims 37-41 correspond to original Group I set forth in the Restriction Requirement of 28 July 2008.

The Examiner respectfully asserts that new claims 37-47 submitted 02 January 2009 all correspond to original Group II, since they all involve five particular molecular markers. Since all of the newly submitted claims belong to a single group, the Examiner has examined all of the claims in the following Office action.

Effective Filing Date

The effective filing date of the instant application is 04 July 2003, the filing date of the earliest foreign priority application, which disclosed all of the instantly claimed elements.

Specification Objections

All specification amendments made in response to the objections below should comply with 37 CFR 1.121(b). New matter should be avoided.

Abstract

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. It is suggested that the first paragraph on page 1 of the specification be deleted, and resubmitted as the Abstract on a separate sheet.

Continuity Data

The specification is objected to for its omission of continuity data. This objection would be obviated by the insertion of the following paragraph on page 1 of the specification, immediately below the title:

---This application is a 371 of PCT/IB04/02491 filed 05 July 2004, which claims foreign priority under 35 USC 119(d) to European application no. 03292057.0 filed 08 December 2003 and European application no. 03291677.7 filed 04 July 2003.---

Headings

The specification is objected to for its omission of section headings. The following amendments to the instant specification would obviate this rejection:

On page 1, immediately above current line 12, insert ---Background of the Invention---

On page 1, immediately above current line 24, insert ---Summary of the Invention---

On page 5, immediately above line 39, insert ---Brief Description of the Drawings---

On page 8, at the top of the page, insert ---Detailed Description of the Invention---

Errors

The specification is objected to for the following errors.

On page 1, line 26, replace "radis" with ---radish---

On page 2, lines 10 and 31, "[A method] according to claim 1" is confusing, because claim 1 has been cancelled from the instant application, and because claim language could change throughout prosecution. It is suggested that this phrase be replaced with ---the above method--- or its equivalent.

On page 7, lines 12 and 26, replace "et" with ---and---.

On page 7, delete lines 28-30 because there is no Figure 18.

On page 8, line 14, replace "Were" with ---The following lines were---.

On page 8, line 15, replace "control" with ---controls---.

On page 8, line 17, replace the asterisk after "napus" with a comma.

On page 8, line 20, replace "Subletal" with ---Sublethal---; and replace "fo" with ---of---.

On page 8, line 21, replace "meioses" with ---meiosis---.

On page 8, line 28, it is unclear what is intended by "quoted plants".

On page 9, line 18, replace "plant" with ---plants---.

On page 10, lines 25-26, it is unclear what is intended by "as for".

Sequences

The specification is objected to under 37 CFR 1.821(d) for its recitation of sequences without the corresponding sequence identifiers. See page 3, line 26 through page 4, line 8.

The sequences recited on pages 4-5 are duplicative of those recited in the Sequence Listing. The full-length versions of the sequences on pages 4-5 should be replaced with their corresponding sequence identifier numbers.

Incorporation by Reference

The apparent attempt to incorporate subject matter into this application by reference to non-patent publications is ineffective because essential material may only be incorporated by reference to published US patent applications or to issued US patents. On page 4 of the specification, lines 6-7; and page 12, lines 29-30; the marker "SG129" is merely characterized on the basis of its description in a non-patent publication. This marker is essential material because it is claimed in claim 41.

On page 11 of the specification, lines 5-6, 9 and 14; the marker "SG34" is merely characterized on the basis of its description in a non-patent publication. This marker is recited in Figure 5.

It is noted that Applicant did not explicitly recite the phrase "incorporated by reference" regarding the essential material above. **Thus, even if Applicant intended to incorporate this material by reference, such incorporation would not comply with 37 CFR 1.57(b)(1) due to the omission of this language.**

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper, **even if the intent to incorporate by reference is present per 37 CFR 1.57(b)(1).** If Applicant had complied with 37 CFR 1.57(b)(1), then Applicant would have been required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating

that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections. Any claim amendments made to address these or other rejections should comply with 37 CFR 1.121(c).

Claims 37, 40 and 42 (part d) are confusing in their recitation of "combination [or use] of five markers selected from the group consisting of" which is confusing, since the group only consists of five markers. Thus, the claims contradict themselves.

Claims 37-38 are indefinite in their recitation in line 1 of "Double low restorer lines" which is confusing, as it is unclear whether multiple, genetically distinct individuals are intended to be claimed in a single claim, which is improper Markush terminology per MPEP 2173.05(h). Amendment of the claims to replace "lines" with ---line--- would obviate this rejection.

Claims 40 and 42 are indefinite in their recitation of relative terms. The terms "good" and "high" in claims 40 and 42 are relative terms which render the claims indefinite. The terms "good" and "high" are not defined by the claim, the specification

does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

In claim 40, the recitation "the use of" does not clearly set forth the particular technique, method steps, or target plants in which the markers are to be used.

In claim 42, the recitation in part (a) of "a deleted radish insertion" encompasses any radish insertion, instead of the radish insertion comprising the *Rfo* restorer gene which is required for the production of producing double low restorer lines.

Claim 46 is indefinite because the preamble does not agree with the body of the claim. The preamble recites a method for producing progeny of hybrid plants, while the body of the claim ends at the production of hybrid plants.

Enabling

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Source of Essential Claim Element

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enabling requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 41 recites the use of the marker "SG129 U". However, as stated above, the specification merely states that this marker was disclosed in a non-patent publication, but does not provide any sequence information. Thus, the instant specification does not enable the claim because it does not provide one skilled in the art the means to make or obtain the claimed marker. A properly executed deposit of the claimed marker may obviate this rejection.

Plant Deposit

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication on page 3 of the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and

registration number, or someone empowered to make such a statement, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, Applicants may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make the same, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Starting Material

Claims 37-44 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to methods for making a double low *Brassica napus* restorer plant with superior female fertility, wherein said

plant comprises the *Brassica oleracea* *Pgi-2* allele instead of the radish *Pgi-2* allele, and wherein said plant presents particular markers, when using R211 as the initial source of the restorer gene, and to the resultant plants made by this method; does not reasonably provide enablement for claims broadly drawn to methods involving the use of any restorer source, or the resultant plants, wherein said plants exhibit enhanced *Rfo* transmission rates or enhanced vegetative vigor, and wherein said plants present the claimed markers and *Pgi-2* allele sources. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to methods for making double low *Brassica napus* restorer plants exhibiting a variety of enhanced agronomic traits including improved female fertility, and presenting five markers of particular sequences, wherein said plants comprise the *Brassica oleracea* *Pgi-2* allele instead of the radish *Pgi-2* allele. In contrast, the specification only provides guidance for methods of making double low *Brassica napus* restorer plants which exhibit enhanced female fertility in the form of enhanced seed set per Figure 3, wherein said plants have their radish *Pgi-2* allele replaced with a *Brassica oleracea* *Pgi-2* allele as the result of chromosomal breakage and rearrangement, when the original source of the restorer gene used in the initial cross is R211.

No guidance is provided for the obtention of plants exhibiting other agronomic improvements such as increased vegetative vigor or increased transmission of the restorer gene. Moreover, no guidance is presented for the obtention of double low

restorer plants exhibiting enhanced seed set, and presenting the claimed markers and sources of the *Pgi-2* allele, following the cross of non-exemplified restorer gene sources.

The production of *Brassica napus* plants which possess transmissible restorer genes while retaining desirable agronomic characteristics, and while retaining the double low trait, is unpredictable. Pellan-Delourme et al (1988, *Genome* 30: 234-238) teach that the presence of a radish-derived restorer gene in *Brassica napus* results in strongly decreased seed set among other problems, wherein the restorer gene interacts unpredictably and non-repeatably with different genetic backgrounds (see, e.g., page 234, paragraph bridging the columns; paragraph bridging pages 236 and 237; page 237, Table 3).

Primard-Brisset et al (2005, *Theoretical and Applied Genetics* 111: 736-746) summarize the state of the art in their teaching that the introduction of the radish restorer allele results in an undesirable increase in glucosinolate content, thus negating the "double low" characteristic of the line into which the restorer allele was introduced. Primard-Brisset et al also teach that deletion of the radish *Pgi-2* allele in *Brassica napus* restorer plants resulted in poor plant vigor and reduced transmission of the restorer allele to progeny. See, e.g., page 736, Abstract and column 2; page 737, column 1, top paragraph and paragraph bridging the columns.

Primard-Brisset et al (2005) also teach that even when utilizing the instantly claimed technique, very few progeny exhibiting sufficient female sterility were obtained. Even among the two female-fertile families obtained, only R211 possessed the instantly

claimed *Pgi-2* allele from *Brassica oleracea*. See, e.g., page 740, column 2, bottom two paragraphs; page 741, top paragraph.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to obtain and evaluate a multitude of *Brassica napus* restorer plants which retain sufficient female fertility or other agronomic characteristics, as well as retaining the desirable double low trait, and presenting the claimed markers and *Pgi-2* allele source, when utilizing a multitude of non-exemplified restorer gene sources.

Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39, 44 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Delourme et al (1992, *Theoretical and Applied Genetics* 85: 222-228, Applicant submitted) or Delourme et al (1999, 10th Rapeseed Conference, Canaberra, pages 26-29, Applicant submitted).

Claims 39 and 44 are drawn to seeds “developed from” *Brassica napus* plants which are double low plants and which comprise a radish restorer gene but not the deleterious radish *Pgi-2* allele. These “developed” seeds may be produced by crossing the above double low restorer plants with any other *Brassica napus* plant of unspecified genotype, including *Brassica napus* plants with no radish restorer genes or with normal

cytoplasms enabling male fertility. The result of said crosses with unspecified *Brassica napus* plants could comprise seeds comprising fertile cytoplasm, no radish restorer allele, and/or no *Brassica oleracea* *Pgi-2* allele; due to meiotic segregation of the restorer allele, and due to the choice of the parent comprising fertile cytoplasm as the female.

Claim 47 is drawn to the progeny of hybrid *Brassica napus* plants produced by crossing the above restorer plant with a cytoplasmically male sterile *Brassica napus* plant lacking the restorer gene. The genotype of the plant to which the hybrid is crossed is not specified, and could include plants which possess neither restorer genes nor sterile cytoplasms. As stated above, the genotype of said progeny could comprise fertile cytoplasm and/or lack the radish restorer gene or the *Brassica oleracea* *Pgi-2* allele.

Delourme et al (1992) teach *Brassica napus* double low plants with either a deleted radish *Pgi-2* allele or a deleted radish restorer gene (see, e.g., page 222, second column, bottom three paragraphs; page 223, Figure 2 and column 1, top two paragraphs; page 227, column 1, penultimate paragraph).

Delourme et al (1999) teach *Brassica napus* double low plants with the radish restorer allele but optionally lacking the radish *Pgi-2* allele, wherein heterozygotes of said plants retained female fertility. See, e.g., page 26, first two paragraphs of the Introduction; page 27, bottom two paragraphs and Figure 1.

Although the prior art plants were produced by a different method than the claimed plants, namely the use of a parent which comprises the radish *Rf* allele and

the *Brassica oleracea* *Pgi-2* allele but not the radish *Pgi-2* allele, the resultant plants are indistinguishable from the claimed plants, for the reasons stated above.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Conclusion

Claims 37-38, 40-43 and 45-46 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest the claimed method of crossing a *Brassica napus* restorer line with a double low line, followed by irradiation prior to meiotic segregation; or the resultant female-fertile, double-low *Brassica napus* restorer plants exhibiting a particular marker profile and comprising the radish *Rfo* allele and the *Brassica oleracea* *Pgi-2* allele but not the radish *Pgi-2* allele.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David T Fox/

Primary Examiner, Art Unit 1638

April 24, 2009